



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,491	01/11/2002	Chaim Sukenik	LUZZATTO 3.0-095	6432

530 7590 04/25/2003

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER

VENIAMINOV, NIKITA R

ART UNIT	PAPER NUMBER
----------	--------------

3736

DATE MAILED: 04/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,491	SUKENIK ET AL.	
	Examiner	Art Unit	
	Nikita R Veniaminov	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 17-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5 & 9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 17-35 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 5 it appears that the Applicant intends to use a Markush group. It is one acceptable form of expression, which is commonly referred to as a Markush group, and should recite members as being "selected from the group consisting of A, B and C". Claim 5 recites the limitation "the anchored SAM" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 4, 5, 7, 9-13 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Sorensen et al. (US 6,500,108 B1). Sorensen et al. ('108) teach a device or temporary, or permanent therapeutic implant, or stent for use in angioplasty comprising a surface layer that has incorporated therein at least one radioactive nuclide; a substrate and a self assembled layer that has incorporated therein at least one radioactive nuclide, and having no other protective layers or coating over said self-assembled layer (see abstract and column 4, lines 8-15); wherein the self-assembled layer is an anchored SAM (see column 5, lines 16-30); wherein the anchored SAM is selected from the group consisting of monolayers anchored by thiol or amine (see column 6, lines 8-41); the device comprising a chemically functionalized SAM incorporating at least one radioactive nuclide such as I-131 (see column 16, lines 26-33) attached at the surface of the device (see column 9, lines 38-48).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 6, 8, 14 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Sorensen et al. (US 6,500,108 B1) as applied to claims 1 and 2 above, in view of Satz (WO 99/51299) cited by Applicant. Sorensen et al. ('108) teach a device or temporary, or permanent therapeutic implant, or stent for use in angioplasty as described in paragraph 5 above, but they do not teach a device, a temporary or permanent therapeutic implant, or a stent comprising a substrate, wherein the substrate is selected from the group consisting of stainless steel, Nitinol, silicon, quartz, cobalt chrome and polymers; wherein a surface layer is formed of a radioactive material that has been activated to induce radioactivity therein after its final formation; and wherein the surface layer has a thickness of less than 10 nm. However, Satz (WO 99/51299) teaches a stent made of Nitinol or polymers (see abstract and page 15, lines 13-19); wherein a surface layer is formed of a radioactive material that has been activated to induce radioactivity therein after its final formation (see page 22, lines 18-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the device of Sorensen et al. ('108) by the substrates of Satz (WO 99/51299), since Sorensen et al. ('108) requires a substrate material and Satz

(WO 99/51299) teaches such substrate materials. Also, it would have been obvious to one of ordinary skill in the art at the time of the invention to determine through routine experimentation an appropriate thickness for implementing the surface layer, including the surface layer within the range of thickness Applicant provides in the claim.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Good ('283); Good ('457); Rowland et al. ('433); Waksman et al. ('882); Berg et al. ('454); Fischell et al. ('698) and Eury ('436).

Art Unit: 3736

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (703) 605-0210. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric F Winakur can be reached on (703) 308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Nikita R Veniaminov
Examiner
Art Unit 3736

April 16, 2003.



ERIC F. WINAKUR
PRIMARY EXAMINER